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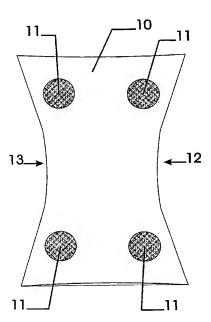
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(54) Title: GARMENT COMPRISING ELECTRODE



(57) Abstract: The invention relates to a garment, adapted to be used as a medical electrode. The garment comprises a tubular body, which comprises at least two different zones. One of these zones is an electrically conductive zone, to be used as the electrode surface of the medical electrode. Another zone is an elastic zone, which comprises electrically non-conductive yarns. This elastic zone assures the position of the electrically conductive zone on the corpus on which the medical electrode is to be used.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

GARMENT COMPRISING ELECTRODE

Field of the invention.

The present invention generally relates to electrodes, and more particularly to medical electrodes.

Background of the invention.

In literature, a lot of medical devices are described, using medical electrodes, e.g. electrodes for transcutaneous muscle and nerve stimulation, electrocardiograph and electroencephalograph. The medical electrode, necessary for each specific application has its own requirement as far as size, shape and electro-conductive properties of the electrode are concerned.

Medical electrodes in general have some major requirements. There should be a perfect contact between the electrode surface and the skin of the corpus, either human or animal. The electrical contact should be located on a well-defined place of the corpus and this place must not change during the use of the electrode. The contact location should be fixed during use. Further, the electrode should be flexible enough to accommodate movements of the corpus, even during use of the electrode.

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These requirements are met to some extent by the electrodes as provided in US 4867166.

In US4664118 on the other hand, one can learn that medical electrodes, used to reduce pain and edema can be provided by making garments enveloping a specific area of a human corpus such as a foot or an elbow, 100% out of conductive material. No solution is offered for electrodes of which the surface does not envelop a part of the body of the corpus.

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US5374283 provides a garment, comprising zones, which are impregnated with electrically conductive material, in order to provide electro-conductive zones.

The use of the electrodes should be easy, and applying the electrode to the corpus should be as simple as possible. This is to reduce the risk for wrongly placed electrodes, in case medical staff decides to give the patient the possibility for therapy without presence of professional assistance.

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Further, the electrodes are to maintain their electro-conductive properties after several times of use and cleaning operations, performed on the garment. This is often a problem using impregnated or coated fibers or garment.

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Summary of the invention.

To meet the mentioned general requirements for a medical electrode, such as perfect electrode-corpus contact, electrode shapes, flexibility during use, fixed contact location during use, simplicity of use and constant conductive properties over time, a garment is provided.

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A garment, as subject of the invention comprises at least two different zones.

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At least one zone is a textile fabric out of electrically non-conductive yarns, e.g. polyamide yarns, polyester yarns, cotton yarns, viscose yarns or other natural or man-made fiber. Purpose of this textile fabric is to be elastic in order to provide a garment which fits closely to the corpus part on which the electrode system is to be worn, e.g. that the inner side of the textile fabric contacts the skin on which it is worn over the whole of its surface. To some extent, elastic fibers can be used to give these zones

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the elastic properties as requested. Elastic fibers can be e.g. polyurethane fibers, such as DORLASTAN® (trademark of Bayer), SPANDEX® (trademark of Globe) or LYCRA® (trademark of Du Pont). Hereafter, these zones are referred to as elastic zones. With electrically non-conductive yarns is meant that the yarns have a linear resistance of more than $10^5\Omega/m$. With linear resistance is meant the resistance between two electrodes, fixed on the yarn on a distance of 1 meter from each other, the yarn being stretched with the less force as possible. Preferably, these elastic zones are knitted, since a garment as subject of the invention out of knitted fabrics show superior elastic properties and fits best to the body on which the electrodes have to be applied.

At least one other zone of the garment comprises one or more electrically conductive yarns comprising metal fibers. In the scope of the invention, a yarn has electro-conductive properties when the yarn is electrically conductive, this is having a linear resistance less than $10^5\Omega/m$.

These electrically conductive yarns comprise metal fibers, preferably stainless steel fibers. Most preferably, bundle drawn fibers are used, e.g. bundle drawn fibers of AISI 316L or AISI 302 stainless steel alloy. The fiber diameter is preferably in the range of 1 to 100 µm, most preferably between 4 and 25 µm. These electrically conductive yarns may consist of such metal fibers, or may consist of metal fibers, blended with other fibers such as e.g. polyamide yarns, polyester yarns, cotton yarns, viscose yarns or other natural or man-made fiber. These fibers may be blended, and afterwards used to provide an intimately blended yarn, or different yarns, each yarn consisting of one type of fibers, may be plied to form a blended yarn. It is understood that all least one type of fibers are to be metal fibers.

A garment as subject of the invention, provided by using these yarns, has the advantage that metal fibers does not tend to migrate or

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disappear during wear of the garment or during cleaning operation.

Constant electrical properties are provided using such metal fibers.

Possibly, this zone can comprise yarns, which comprises polyurethane fibers. These zones are hereafter referred to as electro-conductive zones. These zones will function as the electrode surface, being in contact with the corpus on which the medical electrode is to be applied. Therefore, these zones are at least present on the inner side of the garment, which is to contact the corpus skin.

The different zones in the garment are combined in such a way that the relative location from one zone to the others is well defined and does not change during use of the garment.

During wear of a garment as subject of the invention, the electro-conductive zones come into close contact with the human or animal corpus, wearing this garment. The electro-conductive zones then can function as electrodes for several different medical purposes, when the electro-conductive zones are connected to the other parts of a medical electrode system, such as a power supply or a signal-monitoring unit. One understands that several other elements could be added to the medical electrode system when applied. As known in the art, an electro-conductive gel can be used between the electro-conductive zones and the human or animal skin, to ensure even more a perfect electric contact between electrode and skin.

The garment so provides one or more electrodes to an electrode system, usually a medical electrode system. These electrode systems can then be used for several purposes, e.g. medical purposes.

A garment as subject of the invention can comprise an elastic zone on which an electro-conductive zone is embroidered, using electrically conductive yarns.

Another garment as subject of the invention comprises one or more different elastic zones, preferably knitted and one or more electro-conductive zones, preferably knitted, which are combined in the garment using confection techniques, e.g. stitching the electro-conductive zone on the elastic zone.

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Another garment as subject of the invention comprises one knitted fabric, which fabric comprising different zones. These different zones can be incorporated in one knitted fabric during one knitting action, providing this knitted fabric. Knitting techniques such as intarsia knitting and jacquard techniques are suitable to knit different zones in a fabric, in case it is made on a flat knitting machine, either when a double or single bed knitting structure is used. This technique can also be used when a tubular knitted fabric is provided on a flat knitting machine. In case the knitted fabric is made on a circular-knitting machine, jacquard techniques can be used to provide the different zones in the knitted fabric.

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On double bed knitting structures, made by means of either flat or circular knitting machines, one can use a knitting structure only providing the electro-conductive zones on the side of the garment, making contact to the skin of the human or animal corpus. On the other side, not contacting the skin of this corpus, no conductive yarns are used, so preventing the electro-conductive zone to come into contact with objects which can disturb the electrode function of these electro-conductive zones. This can be done by selectively knitting only the electro-conductive yarns locally on one needle bed of the knitting machine (where the electrode is to be located in the garment), whereas the non-conductive yarns are knitted on the other needle bed. Non-conductive yarns are used to connect knitted fabric on both needle beds.

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On single bed knitting structures, made either on flat or circular knitting machines, one can use a knitting technique, e.g. plating techniques or swanskin-type knitting structures. This to provide the electro-conductive zones on one side of the garment to make contact to the skin of the human or animal corpus. On the other side of the garment, not contacting the skin of the corpus, non-conductive yarns are used, so preventing the electro-conductive zone to come into contact with objects which can disturb the electrode function of the electro-conductive zones.

A person skilled in the art now understands that it is not obvious to combine yarns having elastic properties and yarns comprising metal fibers. The introduction of metal fibers in a yarn limits, if not takes away, all elasticity from the yarn, which makes a combination with elastic yarns not obvious due to the different elongation and transforming behavior.

A garment as subject of the invention can be provided by confection of a flat or pre-shaped textile fabric, or the textile fabric can be automatically shaped during one knitting action, using appropriate knitting techniques. In order to facilitate confection, a knitted fabric may also be pre-shaped by the knitting action using appropriate knitting techniques, e.g. increasing or decreasing the number of stitches locally, or changing gradually the tension on the knitted yarn.

Garment is to be understood in the broadest way, being e.g. socks, stockings, T-shirts, shirts, panty hoses, gloves and caps, but also orthopedic and medical garments such as knee- and elbow bandages or tubular bodies to cover arms, legs, wrists, ankles, chests, belly, in total or partially.

A garment as subject of the invention is meant to be applied to a human or animal corpus. The dimension and shape of the garment as subject of the invention, together with the elastic properties, are chosen to cover

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closely the part of the corpus on which one or more electrodes have to be fixed.

A garment as subject of the invention preferably comprise a tubular body, which on its turn comprise electro-conductive and elastic zones. This tubular body encircles the part of the corpus to which the electrodes have to be applied. In order to facilitate the dressing properties of the garment, the tubular body may be opened end closed during dressing e.g. by zippers, buttons, "loop-and-hook" tapes such as VELCRO®, registered trademark of Velcro Industries BV, or other means. These devices may also serve to slightly change the dimension of the garment, so the garment fitting better to the body volume on which the electrode have to be applied.

The electro-conductive zones are localized in the garment in such a way that these zones appear on the places where electrodes have to be present during the wear and use of the electrode system. One understands that the electrical properties, surface and shape of these electro-conductive zones may be chosen in function of the therapy for which the electrode system is used, e.g. transcutaneous nerve and/or muscle stimulation, monitoring of vital signals, curing or preventing patients suffering from bedsores, diabetes feet, carpal tunnel syndromes, transcutaneous drug administration, to improve blood circulation...

The elastic zones are localized in the garment in such a way that these zones fix the garment, including the electro-conductive zones, on a part of the corpus. These elastic zones also ensure to some extent the physical and electrical contact of the electro-conductive zones on the corpus. One understands that the elastic properties of these elastic zones are chosen in function of the shape and part of the corpus on which the electrode system is to be used. Also, these properties are chosen in such a way that the normal motion of the part of the corpus is

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not restricted to a large extent and negative aspects, such as arterial blocking, are prevented.

Even more, these elastic zones can have a therapeutically goal on there own, like functioning as a support of pressure bandage.

Some attention should be paid to the connection of the other parts of the electrode system to the electro-conductive zones. The lead wires, which connect the electric circuit of the electrode system to the electroconductive zones, can be connected to the electro-conductive zones by techniques known in the art. In case of a knitted fabric, they preferably are integrated in the knitted fabric in such a way that one end of the lead wire, to be connected to the electric circuit of the electrode system, extends outside the garment. The other end of the lead wire can be guided through the garment to one or more electro-conductive zones, where it connects the electrode system to the electrically conductive varns, used to provide the electro-conductive zones, e.g. by embroidering the lead wire e.g. by following a zigzag-stitching path, ending at one or more electro-conductive zones of the garment. Alternatively, when the electro-conductive and elastic zones are provided during the same knitting action, the lead wire can be integrated in the knitted structure of the garment, e.g. via tuck stitches, plating techniques or other knitting techniques.

It is clear that for each electro-conductive zone, a separate lead wire can be used, or those different electro-conductive zones can be connected to each other in a parallel or serial way.

If the electro-conductive zones are visible on the outer side of the garment, which is the side that is not to contact with the corpus, an electrically non-conductive material can be used to be worn over the electrode system as subject of the invention. This to prevent the electro-

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conductive zones to come into contact with objects which can disturb the electrode function of the electrode system during use of this electrode system.

Besides the mentioned flexibility, providing of the skin contact and the location of the medical electrode versus the corpus, the risk on incorrect use due to incorrect location of the medical electrode on the corpus is minimized. This is because it is very clear to the potential user how the medical electrode should be applied. Since the medical electrodes are incorporated in the garment itself, they will automatically be in the right place when the garment is worn, so few mistakes can be made.

Brief description of the drawings.

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The invention will now be described into more detail with reference to the accompanying drawings wherein

- -FIGURE 1 is view of a knitted fabric, comprising different zones.
- -FIGURE 2 is a schematic view of the knitting report to provide a knitted fabric having two different zones.
- -FIGURE 3 is a schematic view of the knitting report to provide a knitted fabric having two different zones.
- -FIGURE 4 is a view of a garment, having an electro-conductive zone on the inner side of the garment, and to be closed to comprise a tubular body.
- -FIGURE 5 is a schematic view of the knitting report to provide a knitted fabric having two different zones, the electro-conductive zone being present only on one side of the knitted fabric.
- -FIGURE 6 is a view of a garment.
- -FIGURE 7 is a view of an electrode system, applied on an upper leg.
- -FIGURE 8 is a view of a knitted fabric, on which an electro-conductive zone is embroidered.

Description of the preferred embodiments of the invention.

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An embodiment of a knitted fabric, out of which a garment as subject of the invention can be obtained, is shown in figure 1.

There is one elastic zone 10, obtainable by using a cotton/polyurethane blended yarn with a count of 50 tex. More specific, it is a two plied yarn, consisting of 97 vol% cotton and 3 vol% polyurethane.

Electro-conductive zones 11 are obtainable by using an electrically conductive yarn with a count of 60 tex. More specific, the yarn is a three plied yarn consisting of 20 weight% stainless steel fibers and 80 weight% polyester, blended intimately through the total yarn volume. The stainless steel fibers used are of alloy AISI 316L, having a diameter of 6.5µm.

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Alternative yarns for the elastic zones 10 have a count between 10 tex and 250 tex, e.g. between 25 tex and 150 tex. The vol% of the polyurethane fibers can go up to 100%. For the embodiment, cotton fibers are used, however, other non-conductive fibers can be applied such as polyamide fibers, e.g. polyamide 6, polyamide 6.6 or polyamide 10.6, polyester fibers, cellulose fibers, wool fibers, acrylic fibers and modacrylic fibers.

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Alternative yarns for the electro-conductive zones comprise metal fibers up to 50 weight% or even more to 100%. Usually, but not necessarily, stainless steel fibers are used. Alloys such as AISI 316 or AISI 316L, AISI 347, or other alloys out of the AISI 300 type are used. Also alloys out of the AISI-400 type, Aluchrome-type alloys or alloys as described in US-4597734 can be used. These fibers can be bundle drawn, as described in patent US-A-3379000, or can be made by shaving them from a coil, as described in patent US-A-4930199 or can be melt extracted. Also metal fibers produced as described in JP 62260018 can

be used. Fiber diameters can vary between 2 and 50µm, e.g. between 6 and 15µm, such as 6.5µm, 8µm or 12µm.

The knitted fabric has two edges 12 and 13 when being knit before confection.

The knitted fabric as shown in figure 1 is obtainable by knitting the yarns on a flat knitting machine gauge 12, using a rib knitting structure, and using intarsia knitting techniques to incorporate the different zones in the same fabric. It should be clear that other knitting techniques and knitting machines could be applied to provide alternative embodiments. Other machine gauges, from 4 to 24 can be used, e.g. a machine gauge 7, gauge 10, gauge 12, gauge 14 or even gauge 16 or gauge 18 can be used. Both single and double bed structures can be used.

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Less preferred, but possible are jersey knitting structures. These can be used to provide tubular knitted fabrics, either on circular or flat knitting machines.

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The electro-conductive zones in the embodiment as shown in figure 1 are of a circular shape. However, other shapes and dimensions can be used to comply with the requirements of the electrodes to be used.

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Different knitting structures, with different knitting reports can be used to provide a knitted fabric as shown in figure 1.

Best, but not necessarily, double bed knitted structures are used. Special attention should be paid to the link between electro-conductive zone and elastic zone in the fabric.

One possible knitting report is shown in figure 2, having only one knitting action 20A in its report. An electrically non-conductive yarn 21 and an

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electrically conductive yarn 22 are knitted, each on a group of needles of the front needle bed 23 and the rear needle bed 24, so providing a knitted fabric with a electro-conductive zone and a elastic zone. A connection between electro-conductive zone, provided by yarn 22 an elastic zone, provided by yarn 21 is obtained by the creation of tuck stitches on the needles 25, located on the edge of both different zones.

An alternative report is shown in figure 3, having two knitting actions 30A and 30B in its report. Also here, the electrically non-conductive yarn 31 and the electrically conductive yarn 32 are knitted, in rib structure, on a specific group of needles on front needle bed 33 and rear needle bed 34. The link between the electro-conductive zone, provided by yarn 32 and the elastic zone, provided by yarn 31 is obtained by knitting yarn 31 on the needles 35 during action 30A, and knitting yarn 32 on needles 35 during action 30B.

An alternative garment as subject of the invention has the electroconductive zone only on the inner side of the garment, making contact with the corpus of the user. The outer side of the garment doesn't comprise an electro-conductive zone, and this to prevent the electroconductive zones to come into contact with objects which can disturb the electrode function of the electro-conductive zones.

Such an alternative garment is shown in figure 4. The inner side 41 of the garment comprises one electro-conductive zone 42, where the outer side 43 of the garment doesn't have an electro-conductive zone.

When the garment is to be used on a part of a corpus, the garment can be opened by means of the zipper 44. The opened garment is placed around the part of the corpus where the medical electrode is to be localized. The garment is closed again by closing the zipper 44, so providing a tubular body to the garment.

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stitches on needles 59.

A knitting report of the zone where an electro-conductive zone is present on one side of a knitted fabric is shown in figure 5. The report comprises 3 knitting actions 50A, 50B and 50C.

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During knitting action 50A, an electrically non-conductive yarn 51 and an electrically conductive yarn 52 are knitted on a specific group of needles on front needle bed 53. In the second knitting action 50B, an electrically non-conductive yarn 54 is knitted on all needles of the rear needle bed 55. Stitches on front and rear bed are then linked to each other by knitting an non-conductive yarn 56 on all needles in both beds, making use of tuck stitches. This way, both electro-conductive zone and elastic zone are present on the front side 57 of the knitted fabric, made on front needle bed 53. On the back side 58 of the knitted fabric, made on the rear needle bed 55, only an elastic zone is to be seen. Electro-conductive zone and elastic zone are linked to each other by using tuck

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By confection of this knitted fabric into a garment (e.g. connecting the knitted fabric to a zipper), a garment as shown in figure 4 is obtained, when the front side 57 is used to provide inner side 41 of the garment and back side 58 is used to provide the outer side 43 of the garment.

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It should be mentioned that a garment, made out of an alternative, having the electro-conductive zones only on the inner side of the garment, meets best the requirements of durability of contact and fixing the electrode to a specific location on the skin of the corpus.

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A person skilled in the art will have noticed that when a knitted fabric is made using only the knitting action 50A, another alternative of a garment can be obtained. This alternative has then a jersey knitting structure and the two different zones are linked by using tuck stitches on needles 59.

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A garment is obtainable by confection of a knitted fabric as part of the invention. The garment as shown in figure 6 can be obtained by sewing edges 12 and 13 of the knitted fabric, shown in figure 1, on each other. The pre-form of the knitted fabric can help to shape the garment to fit better with the corpus part on which the electrode system, using a garment as subject of the invention is to be used.

An alternative way of obtaining a garment as subject of the invention is that the garment is made automatically by knitting the object to its shape as it is to be used. Such an alternative electrode system is shown in figure 7, where a garment as subject of the invention is a tubular body, knitted as a tube using jersey knitting structures, in such a way that edge 71 and 72 have a different diameter. In this example, the shape of the knitted tubular body is chosen to fit closely to the surface of the leg on which it is to be worn. Electro-conductive zones 73 are connected with the electric circuit of the medical electrode system 74 by means of two lead wires 75. These lead wires can be incorporated in the knitted structure by making stitches together with the electrically non-conductive yarns of elastic zone 76 from the electro-conductive zones 73 up to the place where the connection is to be made.

An alternative garment as subject of the invention is shown in figure 8. An elastic zone 81 is embroidered with an electrically conductive yarn 82 in such a way that an electro-conductive zone 83 is provided. Electrical current, necessary for the electrode action of the electro-conductive zone 83, is provided to the electro-conductive zone by a lead wire 84. This lead wire 84 is e.g. an electrically conductive yarn out of stainless steel fibers or Cu-fibers. This lead wire 84 can be stitched on the elastic zone 81 using a zigzag pattern, to provide to the lead wire the possibility to elongate, enough to overcome the elongation of the elastic zone 81 when stretched.

CLAIMS

1. A garment, adapted to be used as a medical electrode, said garment comprising at least two different zones characterized in that at least one of said zones being a electro-conductive zone to be used as an electrode, said electro-conductive zone comprises metal fibers; at least one other of said zones being an elastic zone, being a textile fabric out of electrically non-conductive yarns.

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- 2. A garment as in claim 1, wherein said elastic zone is knitted.
- 3. A garment as in claim 1 or 2, wherein said metal fibers are stainless steel fibers.

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- A garment as in claim 1 to 3, wherein said electro-conductive zone is knitted.
- A garment as in claims 1 to 4, wherein all of said zones are provided by one knitted fabric.
 - 6. A garment as in claim 1 to 3, wherein said electro-conductive zones are embroidered on one or more of said elastic zones.
- A garment as in claims 1 to 6, wherein said at least one of said elastic zones is a pre-shaped by knitting techniques.
 - 8. A garment as in claim 1 to 7, wherein that lead wires, connecting power source to said electro-conductive zones, are integrated in said garment by embroidering.

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- 9. A garment as in claim 1 to 7, wherein lead wires, connecting the electric circuit of the electrode system to said electro-conductive zones, are integrated in said garment by knitting techniques.
- 5 10. A garment as in claim 1 to 9, wherein said electro-conductive zones are only present at the inner side of said garment.
 - 11. A garment as in claim 5, 7, 8, 9 or 10, wherein said electroconductive zones are only present at the inner side of said garment by knitting techniques.
 - 12. Use of a garment as in claim 1 to 11 to provide an electrode to an electrode system.
- 13. Use of a garment as in claim 1 to 11 to provide an electrode to a medical electrode system.

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14. An electrode system, comprising a garment as in claim 1 to 11.

